

User Guide

Chloride Ion analyzing by coulometric titration in medical and pharmaceutical field

CHLORIDMETER CM 20



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2 Notes, Safety Notices and Warnings

The symbols and abbreviations defined below may appear on the packaging material, on the serial number plate or in the operating instructions:



In-vitro diagnostic device



This product meets the requirements of EEC Directive 98/79 relating to in-vitro diagnostic devices.



Attention (refer to documentation)!
Please follow the safety notices in the equipment operating instructions.



"Use by ..." The date that follows indicates the expiration data as *year-month*.



The name of the product batch follows.



Article number or order number

The following pages provide a step-by-step introduction to using, maintaining and servicing the measurement equipment. Passages requiring special attention are marked as follows:



This symbol warns of the danger of corrupting measurement results, for example, by improper use of measuring vessels.



This symbol warns of the danger of damaging the unit or the measurement system, for example, as a result of improper servicing.



Note or tip.

Subject to errors and technical changes.

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Chloride Meter Model Chloridmeter CM 20 / 2009

August 2012 Version 1.07

3 Introduction

3.1 Application Fields of the Chloride Meter

The Gonotec Chloridmeter CM 20 Chloride Meter is a non-invasive in-vitro diagnostic device. It is used to determine the chloride concentration in sweat, urine, serum and other body fluids. Its purpose is to provide information to help identify, diagnose, monitor and treat physiological conditions, states of health, and illnesses.

The equipment may only be operated by specialists or those persons whose training or skills have provided them with the necessary practical experience (see MPBetreibV: German Medical Devices Operator Ordinance).

3.1.1 Application Restrictions of the Chloride Meter

Please ensure that no other halogens, such as **fluoride**, **bromide** or **iodide** are present in the samples. Also, **no oxidizers** may be added to the samples.

Plausibility checks of the results must be performed by the doctor by means of the pertinent literature.

3.2 Chloride Meter Measurement Method

The Gonotec CM 20 chloride meter operates according to the principle of coulometric titration. Two silver electrodes—the generator electrodes (anode and cathode)—are dipped into a measuring vessel filled with working solution. The working solution consists of an acid buffer and a colloid stabilizer that keeps the silver chloride, which arises later on, in suspension.

Since the buffer does not contain any silver ions, the silver ion concentration, and thus the indicator current (see below) is brought to a specific end point. By means of a constant current (generator current) between the two silver electrodes, a constant amount of silver ions is released at the anode. The silver ion concentration is maintained by the measurement electrodes (indicator electrodes), which are dipped into the solution. By adding a chloride sample, the free silver ions form a non-soluble silver

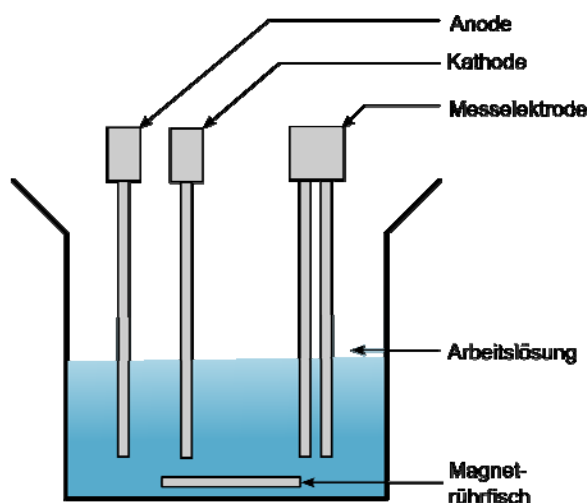
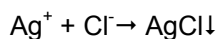


Fig. 1 Schematic Drawing "Coulometric Titration"

Introduction

chloride precipitate together with the free chloride ions of the sample.



The indicator current drops and by controlling the generator current silver ions are released until all chloride ions are precipitated as silver chloride. This restores the original silver ion concentration (end point).

The period of flow of the generator current is measured during the titration process and is proportional to the chloride ion concentration.

Depending on the type of sample, no more than 50 measurements should be carried out using one batch of working solution.

3.3 Specifications

Measurement display	0 - 999 mmol/l
Measuring range	10 - 999 mmol/l
Resolution	1 mmol/l over the entire measurement range
Sample volume	20 µl (nominal)
Reproducibility	± 2 digit, 20 µl sample amount at 100 mmol/l
Linearity	±1 mmol/l or ±1% between 10 - 299 mmol/l

3.4 Unpacking the Chloride Meter

After receipt of the shipment, the chloride meter should be immediately unpacked and checked for obvious signs of damage sustained during shipping. If any damage is found, notify the manufacturer or your distributor:

Gonotec GmbH	Tel.: +49 (0) 30 7809588-0
GSG-Hof Reuchlinstr10-11	Fax: +49 (0) 30 7809588-88
10553 Berlin	E-mail: contact@gonotec.com
GERMANY	Web: www.gonotec.com

Toll-free service number for Germany: 0800 / 7846027

The packaging for this equipment was specially designed to ensure safe and hygienic transport. The packaging is re-usable. Please save the packaging in case the unit needs to be shipped back to Gonotec for repairs or servicing.

This will save you the time and money needed to find equally suitable packaging.

3.5 Packaging Contents

Check to make sure the contents of your shipment are complete. We cannot accept responsibility for any missing items reported at a later date.

Accessories and consumables included in the shipment

	quantity	Item number	Item
Packaging Contents	1	60.00	Chloridmeter CM20
	1	60.3.0010	Anode—silver electrode
	1	60.3.0020	Cathode—silver electrode
	1	60.3.0030	Measurement electrode
	1	60.9.0001	Titration beaker— <i>special beaker</i>
	1	60.9.0002	Magnetic stir bar
	1	60.9.0003	Magnetic stir bar retriever
	1	60.9.0004	Silver cleaning cloth with oxidation protection
	1	60.9.0010	Acid buffer solution (37x10 ml) and stabilizer (1x30 ml)
	1	60.9.0100	Standard solution 100 mmol/l; packaged in 10 ampoules each
	1	20.9.0100	Power cable
	1		Quick Start Guide
	1		User Guide

A complete listing of accessories and consumables is located in the appendix.

4 Design of the Chloride Meter

4.1 Overview of Display and Connectors

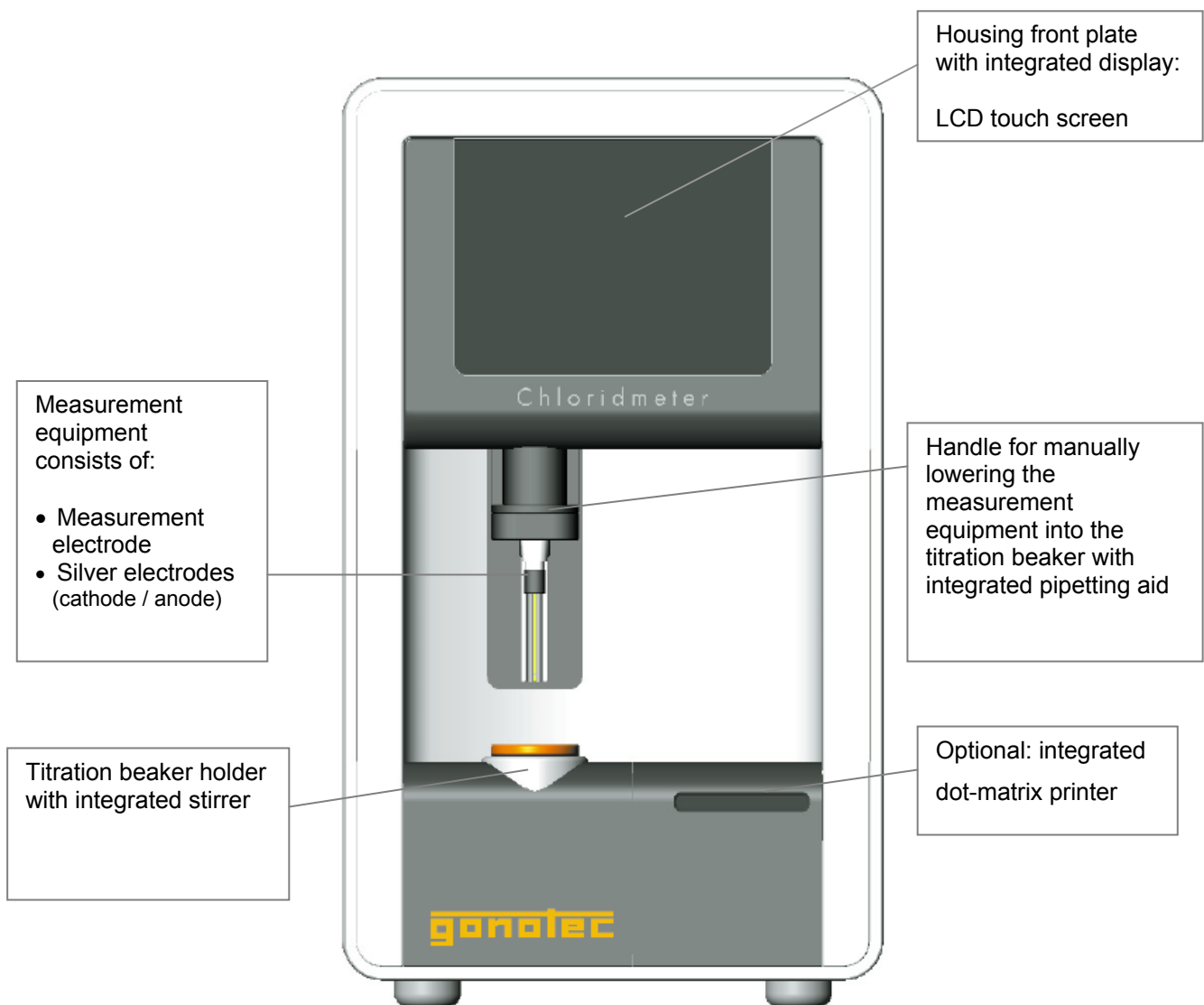


Fig. 2 Frontal view of the chloride meter

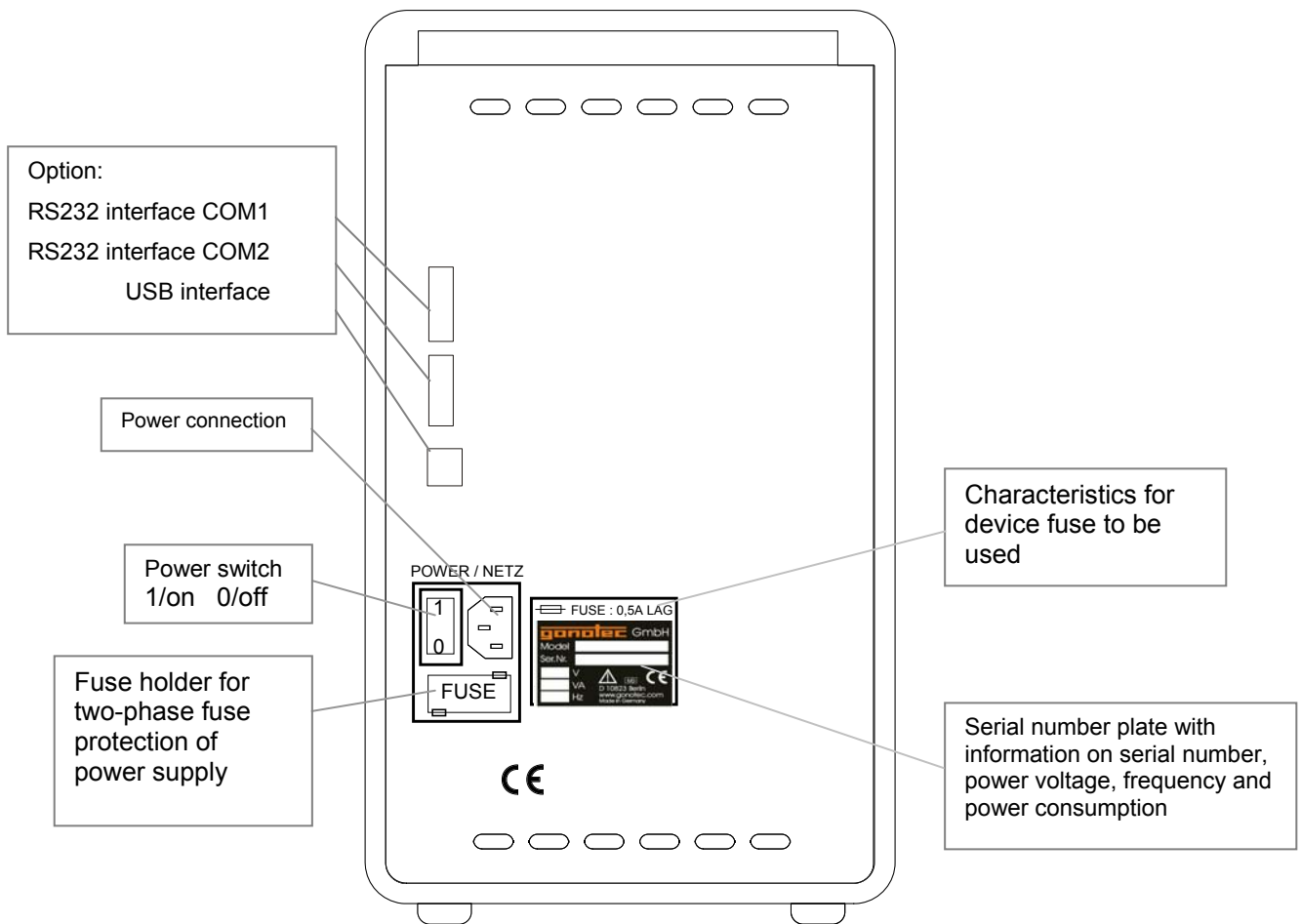


Fig. 3 Rear view of the chloride meter

4.2 Power Supply

Autoselective power supply: 100-120 VAC / 200-240 VAC, 50-60 Hz

Power consumption: 20 VA

4.3 Dimensions and Weight

Dimensions (width x depth x height): 205x220x360 mm

Weight: approx. 5.7 kgs.

5 Setup and Initial Operation

Place the chloride meter onto a flat and solid surface, such as a laboratory table. Avoid direct sunlight onto the LCD touch screen so that instructions and measurement results can be easily read.

Use the power cord provided to connect the chloride meter from the power input socket at the rear of the unit **to an earthed wall power outlet**.



It is also important to ensure that the voltage indicated on the serial number plate matches that of your electricity network. Incorrect voltage will cause the fuse in the power supply unit to blow.

Turn on the chloride meter at the power switch at the rear. After a short self-test, the Welcome screen appears on the touch screen display. This screen is made up of three touch-sensitive fields: INFORMATION, MEASUREMENT and SETTINGS.

5.1 Safety and Handling Information

The chloride meter is an electric laboratory measurement device. It should therefore be handled according to the safety provisions and precautions for electric measurement, control, and laboratory equipment.

Warning: an apparatus with CLASS I construction shall be connected to a mains socket outlet with a protective earthing connection.

Where the mains plug or an appliance coupler is used as the disconnect device, the disconnect device shall remain readily operable. To disconnect the equipment from the mains remove the mains plug from the mains outlet.



If the equipment is to be **decommissioned**, make sure it is sufficiently **disinfected**. This will make sure that the equipment has been **decommissioned** in accordance with **local accident prevention guidelines**.

For cleaning and decontamination of the device and its surface, commercially - in clinical chemical laboratories commonly used detergents, such as Mikrozid® AF Liquid, Bacillol® plus, 3% Korsolex® plus, 4% or similar, are recommended. These are also recommended by the "Robert Koch Institute" for IVD-laboratory devices.

The unit does not emit harmful substances either during operation or when switched off.

Symbols on the unit and its serial number plate meet the requirements of the following standards: DIN EN 61010-1, DIN EN 61010-2-101, DIN EN 61326, DIN EN 62304, DIN EN 62366, DIN EN 591, DIN EN 375 and DIN EN 980 (harmonized standard for medical devices according to § 3 No. 17 of the German Medical Device Law MPG).

Regarding the checking of meters, please refer to the applicable laboratory guidelines in this regard.

5.2 Known Risks during Use

An acid buffer and a stabilizer solution are used during measurement. Make sure you read the attached safety data sheets concerning appropriate safety measures and handling of these solutions.

6 Menu Structure of the Chloride Meter

Brief illustration of handling principle

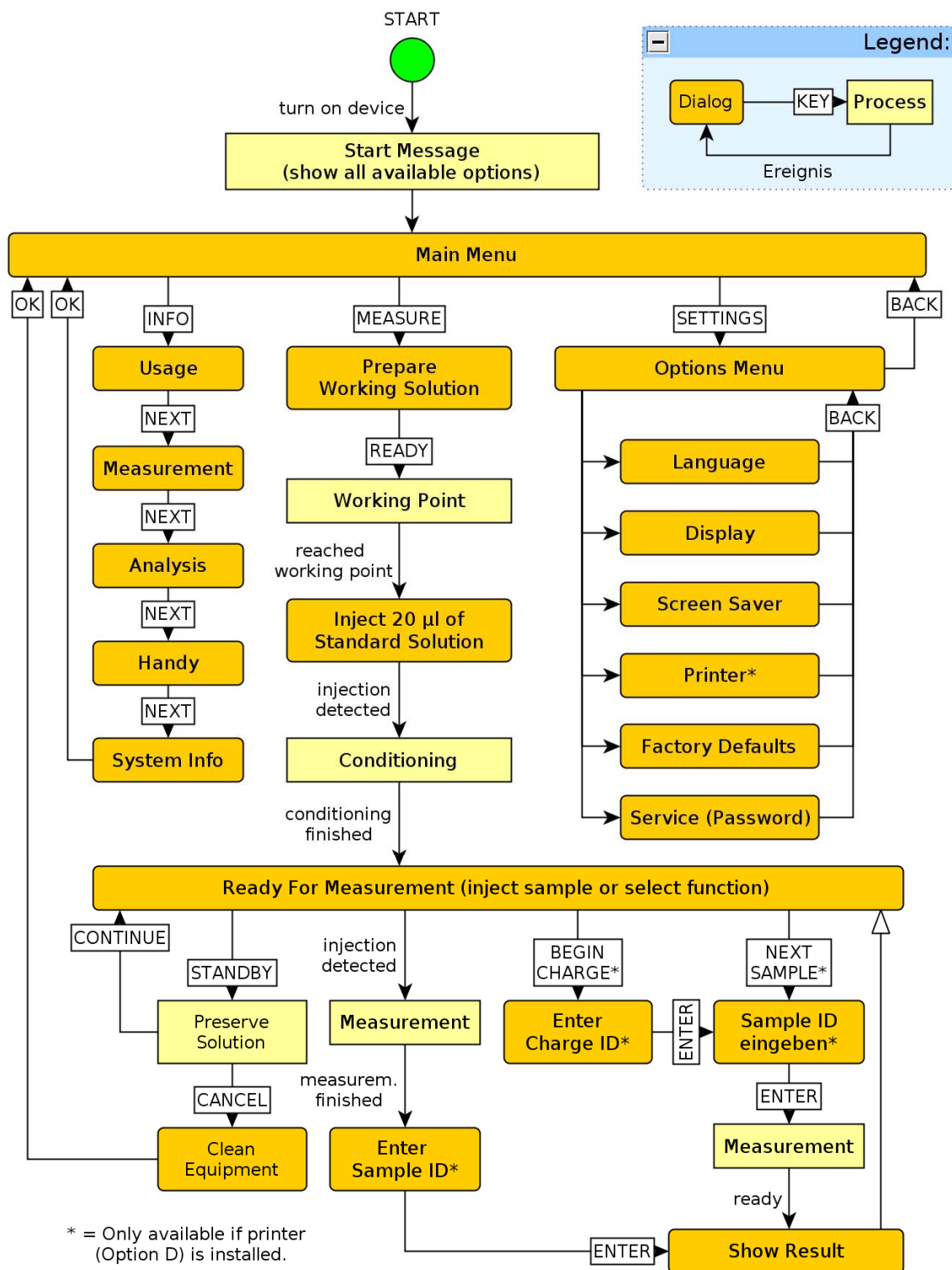


Fig. 4 Menu Structure

6.1 Display and Keypad Overview



Fig. 5 Touch screen

6.2 Menu Functions

Operating the CM 20 chloride meter is very easy using the touch screen display. After you have turned on the equipment, you can initially select between the menu items **Information**, **Measurement** or **Settings** by touching the corresponding symbol. In the **Information** menu item, you will find brief information about your system. To continue, touch the CONTINUE field. At the end, you quit the menu item and will return to the start.

In the **Settings** menu item, you can perform basic settings; to leave this item, press BACK. Setting options include language, display, screen saver, factory settings and internal settings.

Language: You can select the language in which the device operates. You can select between German and English.

Display: You can adjust the contrast of the device. Make sure that the device is set up such that no direct sunlight is directed at the screen.

Screen saver: You can select the amount of time until the screen saver activates, from 30 seconds to 10 minutes, or you can disable it completely.



In order to avoid damage to the screen, we urgently recommend that the screen saver is used!

Printer: If the device is equipped with a printer (Option D) you can trigger a paper feed when you have mounted a new paper roll. And you can select if Charge ID or Sample ID will be generated automatically or must be entered manually (alphanumeric or numeric). With automatic numbering the device restarts counting at midnight every day with Charge ID 1 respectively Sample ID 1. Within each Charge the automatic Sample ID starts with 1 too.

Protocol Port: If the device is equipped with the Option COM you can choose a data port for data transmission to PC.

Factory settings: Here, you can return the equipment to the factory settings.

Note: The device will switch to English mode.

Lab: Here, you can enter or change the date and time.

Password protection is possible. At initial operation a password can be freely selected by the supervisor.

Note: A lost password can only be reset by the manufacturer or its authorized service provider.

Service: Only accessible by the manufacturer or by a service partner.

When you quit Settings, you will return to the start. Now you can begin with your measurements.

Touch the MEASUREMENT button to start the procedure. The system starts the measurement sequence and leads you through it using simple instructions until a successful measurement has been carried out. Please refer to Chapter 8 "Measurement of a Sample Solution" for information on the precise sequence.

7 Calibration

The chloride meter is delivered in calibrated condition from the factory. Calibration by the user is not required.



Calibration is checked and if necessary recalibration is performed during an annual maintenance check or meter check by the manufacturer or service agency.

8 Measuring a Sample Solution

After turning on the device, you can start using the chloride meter immediately.

8.1 Preparation

1. Add 20 drops of Gelatin solution (stabilizer, 60.9.0010) to a 10 ml flask of acid buffer solution (60.9.0010), seal the buffer flask shut and carefully turn it over a few times.
2. Make sure that the chloride meter is turned on and touch the MEASUREMENT field on the touch screen display with your finger.
3. On the display you will be asked to add the working solution that you have just prepared (buffer and stabilizer) and the magnetic stir bar (60.9.0002) to the beaker (60.9.0001) of the CM20 chloride meter.
4. Place the filled measurement vessel into the trough provided for it in the chloride meter.
5. Move the measurement sensor unit downward into the working solution.
6. Now touch the READY field.

Note: If you do not wish to perform a measurement, you can end further measurement by touching the CANCEL field; this will take you back to the Welcome screen.

7. In the following display, you will be asked to wait until the system has reached its working point. A runtime display under the message visualizes this process. Then, the system must be conditioned.

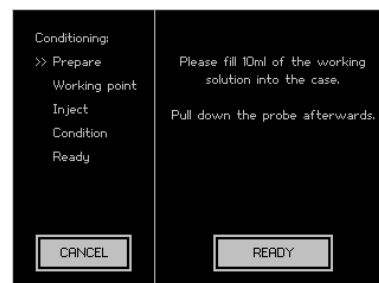


Fig. 6 measurement - start

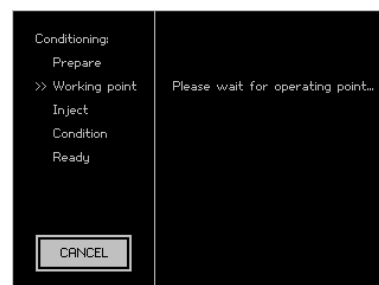


Fig. 7 measurement – working point

8.2 Conditioning

Conditioning must always be done when the chloride meter is turned on, a measurement procedure or a measurement series has been canceled or if the working solution has been changed.

8. After the working point is reached, you will be asked to pipette 20 µl (0.02 ml) of the standard solution (100 mmol/l, 60.9.0100) into the working solution.

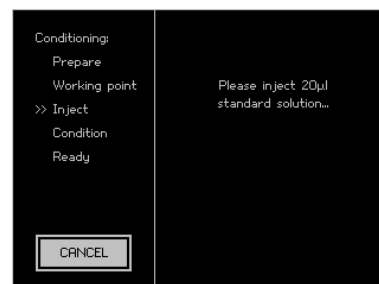


Fig. 8 measurement – standard solution

9. To do so, place an OPC ampoule (One-Point-Cut ampoule) of the 100 mmol/l standard solution onto a flat surface and hold it steady with one hand. With the other hand, break off the head of the ampoule carefully and with only slight pressure across the printed point on the neck of the ampoule.



Note: Do not try to break off the OPC ampoules across an arbitrary point of the neck or with force. You could be injured by the shattering of the entire ampoule.

10. Now place a correctly-sized pipette tip onto your 20 µl fixed volume microliter piston pipette or your multivolume pipette set to 20 µl. Press the piston of the pipette into the pipette up to the first pressure point and hold the piston there. Lead the pipette tip into the standard solution and leave the pipette tip in the solution during the filling phase. Allow the piston of the pipette to slowly and smoothly retract until the piston is relocated in its initial position. Make sure that you do not take in any air! Wait for a second and then remove the pipette from the solution. There are now exactly 20 µl of solution in the pipette tip. If you see drops on the outside of the pipette tip, carefully remove them with a lint-free paper tissue—do not draw off any solution from the pipette tip (through capillary forces of the paper tissue)—or repeat the process with a new pipette tip.
11. Place the pipette with the filled pipette tip into the working solution located in the chloride meter. Use one of the two guides at the measuring sensor unit as a guide. Dip the tip into the working solution and press the piston up to the second pressure point in order to completely eject the solution. Pull the pipette out of the working solution with the piston pressed. Make sure that you do not pipette the solution at the electrodes or at the wall of the beaker. Pipette the solution directly into the working solution close to the center.
12. The chloride meter recognizes the addition of the standard solution automatically, whereupon the message PROCEEDING WITH CONDITIONING-... will display.
13. After the conditioning is completed, a measurement should be taken using the 100 mmol (60.9.0100) standard to check the calibration.

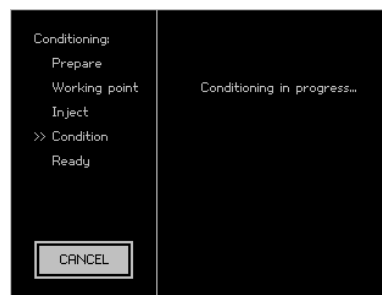


Fig. 9 measurement - conditioning

8.3 Executing a Sample Measurement (without Printer)

Chloride meter CM20 without option D or deactivated printer – this can be done by using the check box “use printer” in Fig. 10.

14. Before each sample series, the calibration of the chloride meter should be checked using the 100 mmol standard solution.
15. After conditioning is finished, add 20 µl of your sample solution (sweat, urine, serum or standard solution/control solution). Follow the instructions from the CONDITIONING chapter with regard to the information on the correct way to add sample.

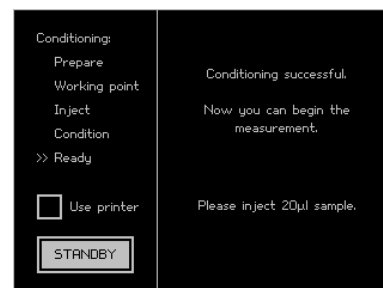


Fig. 10 sample measurement

16. The chloride meter automatically recognizes that sample has been added, and automatically begins the measurement. The message PROCEEDING WITH CHLORIDE MEASUREMENT... will display. You can track the measurement visually through the incremental display value. If you would like to cancel the measurement, touch the CANCEL field.
17. After the measurement is finished, the message THE MEASUREMENT WAS SUCCESSFUL will display, and the result value is indicated on the display in mmol/l.
18. If you would like to take another sample, pipette another 20 µl sample into the measuring vessel. If you would like to end the measurement series, touch the END field on the touch screen display.

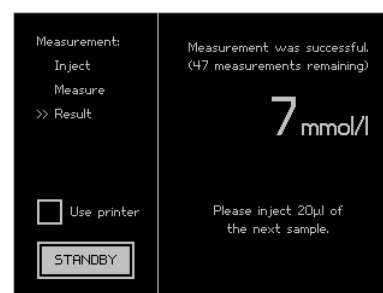


Fig. 11 successful measurement



Note: If the chloride meter does not automatically begin upon addition of the sample, it is probably because the chloride concentration is less than 10 mmol/l. Increase the concentration using the standard solution by adding 20 µl of the standard solution (60.9.0100). Subtract 100 mmol/l of the standard from the final result.

8.4 Executing a Sample Measurement (with Printer, single-probe)

If your device is equipped with a printer (Option D) you can use it to log the measurement results. The result of every sample will be printed if you turn on the option USE PRINTER in the screen at the beginning of each measurement run. Every sample shall get a unique identifier (Sample ID). This can be done manually or automatically.

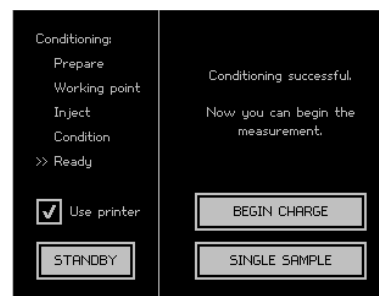


Fig. 12 measurement – printer modus, single-probe

- 1 Before each sample series one should check the calibration of the chloride meter by running a test measurement with a 100 mmol standard solution.
- 2 After successful measurement please press the SINGLE SAMPLE button on the screen. If the automatic sample numbering was activated you will be asked to inject the sample. In manual sample numbering you will be asked to enter the Sample ID and then to inject the sample. Alternatively you can inject the sample directly without pressing any button. The measurement then starts automatically and you will be asked for the Sample ID after the measurement has finished.
- 3 Now inject 20µl of the sample (sweat, urine, serum or rather a standard or a control solution). Please consider the advices in the chapter CONDITIONING respectively the correct way to inject a sample.

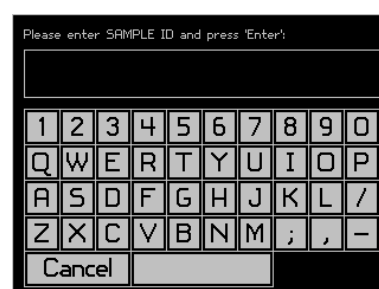


Fig. 13 measurement – probe numbering

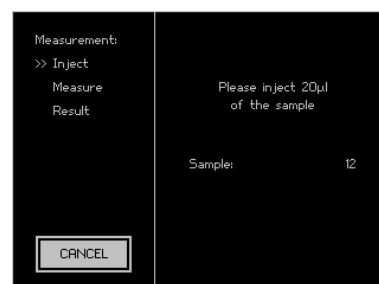


Fig. 14 measurement – sample injection

- 4 The chloride meter automatically detects the injection and will start the measurement. While the measurement is running the message **CONDITIONING IS RUNNING...** will be shown on the display. You can track the measurement process by reading the increasing measure value. If you like to abort the measurement please press the CANCEL button.
- 5 After the successful measurement the message **MEASUREMENT SUCCESSFUL** and the measurement result value in mmol/l will be displayed. Additionally the result will be printed on paper.
- 6 If you like to measure another sample please just inject 20 µl of the next sample into the measurement vessel. If you like to end the measurement press the STANDBY button on the touch screen to enter the standby mode and then press CANCEL.



Fig. 15 measurement – sample reading

8.5 Executing a Sample Measurement (with Printer, Charge)

If your device is equipped with a printer (Option D) you can use it to log the measurement results and organize them in charges. Every charge shall have a unique charge number (Charge ID) and every sample in this charge shall have a unique Sample ID within this charge. Both can be done manually or automatically.

- 1 Before each sample series one should check the calibration of the chloride meter by running a test measurement with a 100 mmol standard solution.
- 2 After successful measurement press the BEGIN CHARGE button on the screen. If the automatic charge numbering was activated as well as the automatic sample numbering, you will be asked to inject the sample. In manual charge and/or sample numbering you first will be asked to enter the Charge ID (and the Sample ID) and then to inject the sample. If you have already started with a charge before you also can inject the next sample of this charge directly without pressing any button. If manual numbering is selected in the settings you will be asked for the Sample ID after the measurement has been finished.
- 3 Now inject 20µl of the sample (sweat, urine, serum or rather a standard or a control solution). Please consider the advices in the chapter CONDITIONING respectively the correct way to inject a sample.
- 4 The chloride meter automatically detects the injection and will start the measurement. While the measurement is running the message CONDITIONING IS RUNNING... will be shown on the display. You can track the measurement process by reading the increasing measure value. If you like to abort the measurement please press the CANCEL button.
- 5 After the successful measurement the message MEASUREMENT SUCCESSFUL and the measurement result value in mmol/l will be displayed. Additionally the result will be printed on paper.

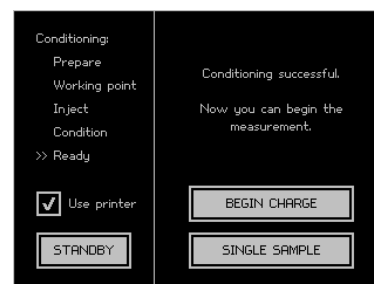


Fig. 16 measurement – printer modus , charge

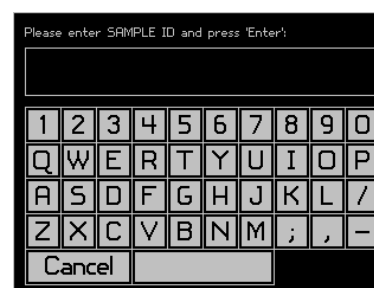


Fig. 17 measurement – probe numbering

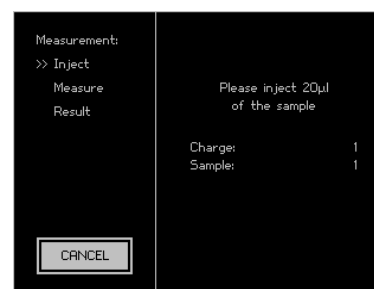


Fig. 18 measurement – sample injection

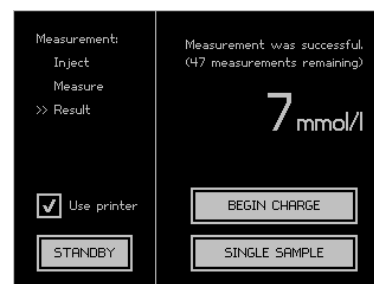


Fig. 19 measurement – sample reading

If you like to measure another sample please just inject 20 µl of the next sample into the measurement vessel. To end a running charge, press END CHARGE. Afterwards the device is in single sample mode again until you begin another charge. If you like to end the whole measurement series press the STANDBY button on the touch screen to enter the standby mode and then press CANCEL.

9 Digital Data Output Interface (Option COM)

If the device is equipped with a digital data output interface (Option COM), you will find three digital output connectors at the rear site of the device.

The upper serial data port COM1 (RS232) can be used to connect a bar code reader. A compatible and ready configured bar code reader can be purchased via Gonotec GmbH (respectively via an authorized dealer).



The use of other bar code readers which are not supplied by Gonotec GmbH is not recommended because of possible incompatibility issues.

The chloride meter CM20 also can log the measured results through the serial data connector in the middle of the interface connector COM2 (RS232).

The relevant data port may be selected under the menu **SETTINGS**, option **PROTOCOL PORT**. In the following display, selection between **COM2** and **COM3/USB** is possible.



The operation of the USB port requires a software driver. In the following there are two options available to install the driver as mentioned below:

- **Automatic installation:** connection of the chloride meter CM20 to a PC via the USB cable and following switch-on. The PC's operating system recognizes the interface, automatically installs the required software driver and then signalizes the successful installation. Now the USB port may be used as additional COM interface.
- **Manuel installation:** The PC does not recognize the chloride meter automatically and/or the operating system is not supplied with the required software driver. In that case please refer to enclosed CD, which contains the installation guide and software driver for the relevant Windows operating system required.



Devices and equipment which should be connected to the RS232 and/or USB interfaces must comply with the relevant safety standards. Wary of the potential damage to man and machine.

Digital Data Output Interface (Option COM)

The following data format will be used for output:

Formatting:	ASCII	a comma character (ASCII 0x2C ","), is used to separate the data columns and the carriage return character (ASCII 0x0d <CR>) to separate lines.
Baud Rate:	transfer speed is 9600 Bits/s.	
Data Format:	8 data bits no parity 1 stop bit	

Before any data output at the beginning of a charge or a single sample measurement the following header will be printed:

charge, sample, date, time, value, device, device-no<CR>

Then the following output will be printed after every successful measurement:

<charge>,<sample>,<date>,<time>,<value>,<device>,<deviceno><CR>

Output Content:

<charge> Charge ID or a minus sign "-" if no charge is running (alphanumeric).

<sample> Sample ID (alphanumeric).

<date> Date of the measurement in English notation "mm/dd/yyyy".

mm	Month, two digits	[01..12]
dd	Day, two digits	[1..31]
yyyy	Year, four digits	[0000..9999]

<time> Time of measurement in English notation "HH:MM".

HH	Hour	[00..23]
MM	Minute	[00..59]

<value> Measurement result without decimal places (in mmol/l).

<device> Alphanumeric device description (e.g. "CM20").

<deviceno> Unique device identifier (alphanumeric).

10 Maintenance of the Chloride Meter

10.1 Replacing the Measurement Electrode or Silver Anode



Pull out the power plug of the equipment!

Risk of electric shock!

For purposes of replacement, the measurement electrode can be manually pulled out downward, and can be inserted upward. Insertion of the plug is easy since the connection pins are designed such that it is impossible to install the contacts the wrong way round.

Note: The measurement electrode can be easily replaced with one hand without the use of additional tools. However, do not insert or remove the electrode at an angle. During removal, the entire measuring equipment could be pulled down with it. Push the measurement electrode up until it is completely engaged (seated firmly).

Titration electrodes are inserted into the colored receptacles of the measurement equipment according to their color marking (red/black).

10.2 Comparison Control Measurements

A comparison control measurement must be carried out and documented according to applicable laboratory guidelines, using a 3-level control solution (e.g. SS-150, Wescor[®], Inc.). If a control measurement deviates from the prescribed target range, the manufacturer or the service agency must be notified.

10.3 Safety Checks

Safety checks should be conducted in accordance with relevant accident prevention guidelines. For annual maintenance (safety checks/meter checks), contact your dealer or Gonotec.

10.4 Meter Checks

Once per year, a meter check and calibration must be carried out by the manufacture or service agency. Nonetheless, the user should perform the following checks:

Control measurements must be carried out in accordance with applicable laboratory guidelines.

Measurement readings and any evaluation results must be logged.

If the system is to be used for immediate diagnostics for patients, RiliBÄK* requires the following:

"In such cases ... a single control sample measurement must be done at least once per week if patient samples are examined through this process during the respective calendar week".* We recommend that the 3-level control solution SS-150 of Wescor[®], Inc. be used.

*s. Guidelines of the German Medical Association for Quality Assurance of Medical Laboratory Investigations Volume7, Feb.15, 2008 Par. 2.1.5

10.5 Internal Quality Checks

A programmable microcontroller monitors the unit's functions. The failure of individual functional groups in the unit results in a malfunction that either outputs an error message or shuts down the unit.

10.6 Settings

10.6.1 Setting the Date and Time

Within the menu *Settings* select *Lab* to change the date and time. The settings are password protected.

The password is set during commissioning the device by a laboratory supervisor.

The password can be changed as often as desired.

Note: A lost password can only be reset by the manufacturer or its authorized service provider.

10.6.2 Function Checking

Only accessible by the manufacturer or by a service partner.

10.6.3 Re-Initialization

When you return the unit to its factory settings, the entire system is re-started and re-initialized.

10.7 Printer Maintenance

Ensure that no foreign objects enter the unit during unit maintenance work. The mechanics and the measurement system could be damaged when restarted.

10.7.1 Printer Paper Change

Press the *paper feed* button to eject any remaining paper from the printer.

Do not pull on the paper since this could damage the printing device.

1. Carefully push against the printer shaft.
The printer unit automatically pushes out
of the housing.
Remove the empty roll core from
the carriage.

2. Insert a new paper roll.
Ensure the correct feed direction of the paper roll (Fig. 6).

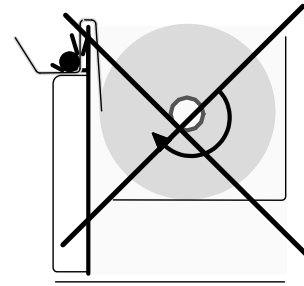


Fig. 20 Incorrect feed direction of paper roll

3. Cut off the end of the paper so that it is even and guide it into the paper slot from above.
Hold the *paper feed* button pressed, until about 2 cms extend from the housing.
4. Push the printer unit back into the housing; a slight latching will be felt.

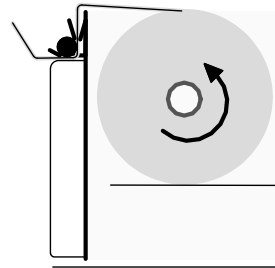


Fig. 21 Correct feed direction of paper roll

10.7.2 Ribbon Change

The ink ribbon cassette must be replaced when the printout no longer has sufficient contrast.

1. Tear off any paper strip from the slot before replacing the ribbon.
2. Press on the right side of the ribbon cassette using light finger pressure.
The cassette is released from the printer.
3. Take out a new ribbon and rotate the rotating knob clockwise with your index finger to tighten the ribbon.
4. Insert the ribbon in the printer. The paper must be between the ribbon and the ribbon cassette. Tighten the ribbon by twisting the knob again.
5. Press and hold the *paper feed* button until approx. 2 cms of the printer paper are protruding from the housing and then close the door.

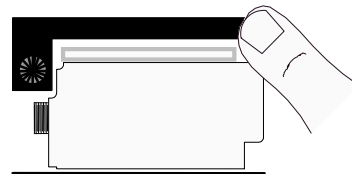


Fig. 22 Replacing the ribbon

10.8 Replacing a Defective Power Fuse



Before replacing a defective power fuse, ***unplug the unit from the power supply! Risk of electric shock!***

To replace the fuses, use a small screwdriver to remove the fuse holder on the rear of the unit. The two fuses can now be replaced. The unit has two-phase protection.

Use so called HBC fuses with a breaking capacity of 1500 A. Others are not allowed!

200-240 VAC power supply: 0.5 A slow/LAG

100-120 VAC power supply: 1 A slow/LAG

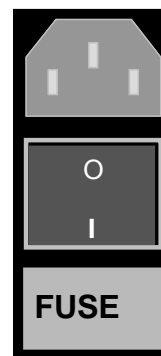


Fig. 23 Power switch



When inserting the fuse holder, it is imperative that ***it is reinserted into its same original position.***

10.8.1 Forfeiture of Measurement System Warranty

Use of non-supported measurement or titration electrodes that will destroy the measurement system, even if done during the warranty period, shall result in forfeiture of the warranty claim of repair or replacement of the measurement system.

11 Error Messages and Troubleshooting

The following explains the error messages reported by the unit along with their possible causes.

11.1 Classification of Malfunctions by Component Group

The following presents an overview of the individual component groups, identifying the function of each component, its potential malfunctions, the effects of the malfunctions on the measurement system, the possible causes of the malfunctions and the procedure for correcting each malfunction.

Conditioning cannot help minimize damage in this case. It is thus of no consequence whether these malfunctions occur during conditioning or during a sample measurement.

Some errors can be remedied directly by the user or an in-house medical equipment technician; other errors require return of the unit to the manufacturer.

Component Groups function	Malfunction	Effect	Possible Cause	Measure
Titration electrode Anode Cathode	- fluctuating measurement values during measurement of the standard	- no plausible measurement values	- contaminated electrodes - mech. defective electrode	- clean the electrodes with the silver cleaning cloth and then rinse with distilled water - replace the electrodes
Measurement electrode	- conditioning not successful	- unable to begin the measurement series	- contaminated electrodes - mech. defective electrode	- clean the measurement electrode with the silver cleaning cloth and then rinse with distilled water - replace the measurement electrode
Working Solution	- conditioning fails	- unable to begin the measurement series	- incorrect or used solution	- use new original solution
Pipette	- fluctuating measurement values	- no plausible measurement values	- pipette defective or incorrect use of the pipette	- examine pipette and examine the handling of the pipette

Table 1 Cause and remedy of malfunctions

12 Buffer, Stabilizer and Standard Solutions

12.1 Provisions of Certification

CE compliance requires that the device together with the buffer, stabilizer and standard solutions and accessories be used in the manner described in this manual. Any deviation from the specifications or independent modifications of the device, the buffer, stabilizer and standard solutions or accessories without the express consent of the manufacturer may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

12.2 Composition

Standard solution FKGO-100 (60.9.0100) contains 100 mmol/l of sodium chloride in distilled water. For precise concentration information, see the analysis certificate for each batch.

The acid buffer consists of a diluted acetic acid/nitric acid solution.

12.3 Safety and Handling Information

12.3.1 Standard Solution

The standard solution is not dangerous according to EC Directive 67/548/EEC.	
Poison class (Switzerland):	F (no poison class)
German water hazard class (WGK):	1 (slightly hazardous to water)
Storage class (German association of chemical industries, VCI):	10-13 (miscellaneous liquids and solids)
Disposal	According to GLP/institute requirements/regulations on the federal, national, and local level

Note: The standard solution consists of **chemicals**. Accordingly, all **precautionary measures and regulations must be adhered to and applied** (do not swallow, do not taste, always wear gloves, etc.).

Container: clear glass OPC ampoules.

Nominal volume: 1 ml

The ampoules have a breaking ring with a breaking ring color (blue dot). The ampoule can be opened manually by breaking it off at this point. Follow all safety precautions for the handling of glass (splintering, breakage, etc.).

12.3.2 Buffer and Stabilizing Solution

The buffer and stabilizing solution are hazardous materials according to EC Directive 67/548/EEC. Information on safety and handling can be found in the attached safety data sheets.

60.9.0010 Acid buffer solution

Container: Screwed cover plastic bottles.

Nominal volume: 10 ml

60.9.0010 Stabilizer solution

Container: Screwed cover dropper bottle.

Nominal volume: 30 ml



Please read the safety data sheets.

12.4 Storage and Shelf Life:

When stored unopened in their original containers at 5°C to 45°C, the consumables have a shelf life up to the expiration date indicated on the packaging.

Do not continue to use the consumables after the expiration date!

12.4.1 Standard Solution

Once the ampoule has been opened, the standard solution shelf life is:
up to ½ hour at + 22°C.

12.4.2 Acid Buffer and Stabilizer Solution (Working Solution)

The shelf life of fresh working solution (acid buffer with stabilizer solution) is a maximum of 14 days when kept in a sealed opaque vessel. Working solution (which contains silver chloride) that is to be used for measuring purposes should be used as soon as possible since it can react photochemically with light (reduction of the precipitated silver chloride into elementary silver). We recommend that a new working solution is prepared for each measurement series.

Appendix

Consumables

Item no.	Item	Packaging unit/qty
60.9.0010	Acid buffer solution (37x10 ml bottles) and stabilizer (1x30 ml bottle)	1
60.9.0100	Standard solution 100 mmol/l NaCl; packaged in 10 ampoules each	1

Accessories and Replacement Parts

Item no.	Item	Packaging unit/qty
60.3.0010	Silver electrode (anode)	1
60.3.0020	Silver electrode (cathode)	1
60.3.0030	Measurement electrode	1
60.9.0001	Titration beaker (special beaker)	1
60.9.0002	Magnetic stir bar	1
60.9.0003	Magnetic stir bar retriever	1
60.9.0004	Silver cleaning cloth with oxidation protection for electrode cleaning	1
30.9.1010	Printer paper for OSMOMAT 030-D/010/auto/CM20	8
30.9.1020	Endless ink ribbon cassette for OSMOMAT 030-D/010/auto/CM20	1
20.9.0165	Data cable for RS232 connection CM20	1
on request	Barcode hand scanner with power supply and cable	1

Classification of the IVD

The chloride meter made by us is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). The chloride meter is not named in Annex II, list A or B, of the Directive 98/79/EEC for in-vitro diagnostics. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, since the unit's intended use does not include personal use.

EC Conformity Statement—Chloride Meter

Gonotec GmbH
GSG-Hof Reuchlinstr. 10-11
D-10553 Berlin

We hereby declare that the chloride meter complies with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the unit acknowledges this.

Date: 01.07.2009

Signature of managing director:

Provisions of Certification

CE compliance requires that the unit is installed and operated in the manner described in this manual. Any deviation from the specifications or independent modifications of the unit without the express consent of Gonotec GmbH may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

Limited Warranty

Gonotec product	Duration of Limited Warranty
Software	90 days
Measurement electrode	180 days
Chloride meter	1 year

A. Extension of the Limited Warranty

- Gonotec guarantees the end user that Gonotec products shall be free from manufacturing and material defects for the above periods of validity from the purchase date. The end user must provide proof of the purchase date.
- For software products, Gonotec's limited warranty applies only to the non-execution of programming instructions. Gonotec does not guarantee that the operation of a product will proceed without errors or interruptions.
- Gonotec's limited warranty applies only to defects that arise during normal operation of the product. It does not apply under the following conditions:
 - Inadequate servicing or improper modification;
 - Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or
 - Use of the equipment in a manner not covered by the product specifications.
- For Gonotec chloride meters, the use of accessories—in particular measurement electrodes and titration electrodes—made by manufacturers other than Gonotec does not void the customer's warranty claims or any customer support contracts between Gonotec and the customer.
If, however, such use results in malfunctions or damages to the chloride meter and the measurement and stirring equipment due to the use of titration beakers, measurement and titration electrodes by others, Gonotec shall assess the normal fees for the time and material required to repair the chloride meter in order to fix such malfunctions or damages.
- If Gonotec is notified within the warranty period of a defect in a software product, in media, measurement electrodes or titration electrodes and if the Gonotec warranty applies to the defect, Gonotec shall replace the defective product. If Gonotec is notified within the warranty period of a defect in a hardware product and if the Gonotec warranty applies to the defect, Gonotec shall repair or replace the defective product at its discretion.
- If Gonotec is unable to repair or replace a defective product to which the Gonotec warranty applies, Gonotec shall refund the purchase price of the product within a reasonable period following notification of the respective defect.
- Gonotec is not obligated to repair or replace a product or refund its purchase price until the customer returns the defective product to Gonotec.
- Replacement products may be new or almost new, as long as their functionality is at least that of the replaced product.
- The Gonotec limited warranty is applicable in all countries in which Gonotec sells the applicable product. The following countries and regions are exceptions: All countries outside the EU. In these countries, the warranty is only valid in the country in which the product was purchased. Contracts for additional warranty services, such as on-site service, may be available from an authorized Gonotec sales partner.

B. Limitation of the Warranty

- TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL ASSUME ANY ADDITIONAL WARRANTY SERVICES OR ACCEPT ANY OTHER CONDITIONS, EXPRESS OR IMPLIED, WITH REGARD TO THE GONOTEC PRODUCTS.

C. Limitations of Liability

- To the extent permissible under the applicable local laws, the legal remedies named here shall be the sole and exclusive legal remedies available to the customer.
- TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS AND WITH THE EXCEPTION OF THE OBLIGATIONS EXPRESSLY NAMED HERE, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL BE LIABLE FOR DIRECT OR INDIRECT, SPECIFIC, INCIDENTAL OR CONSEQUENTIAL LOSSES, WHETHER BASED ON A CONTRACT, A TORTIOUS ACT OR ANOTHER LEGAL THEORY, AND NOTWITHSTANDING PRIOR NOTIFICATION OF THE POSSIBILITY OF SUCH A LOSS.

D. Respective Jurisdiction

- This warranty statement guarantees the customer certain legal claims. The customer may have other legal claims that go beyond those outlined here. Such claims vary by state in the US, by province in Canada and by nation elsewhere in the world.
- Elements of this warranty statement that conflict with local laws can be regarded as amended to comply with the applicable laws. For this reason, certain warranty exclusions and restrictions outlined here may be of no relevance to the customer. In some states of the US, in some Canadian provinces and in some countries outside North America, for example, the following national laws apply:
 - Exclusion of the fact that the warranty exclusions and restrictions named here restrict the legal rights of a customer (for example: Great Britain)
 - Restriction of the possibilities for manufacturers to enforce such warranty exclusions and restrictions
 - Granting of additional warranty claims for the customer, fixing of the validity period for implied warranty services that the manufacturer may not exclude, or nonadmission of restrictions relating to the validity period for implied warranty services
- THE FOLLOWING APPLIES TO CONSUMER TRANSACTIONS IN AUSTRALIA AND NEW ZEALAND: THE CONDITIONS OF THIS WARRANTY STATEMENT NEITHER EXCLUDE LEGAL RIGHTS APPLICABLE TO THE SALE OF GONOTEC PRODUCTS TO SUCH CUSTOMERS NOR REPRESENT A RESTRICTION OR AMENDMENT OF SUCH RIGHTS, BUT INSTEAD REPRESENT A SUPPLEMENT TO THESE RIGHTS, EXCEPT TO THE EXTENT PERMISSIBLE UNDER THE LAW.

Returning Parts for Warranty Repair or Credit

All products returned for repair or credit must be prepared as follows:

- 1 Call or write to request a free return order for equipment that is being returned for warranty repair or credit.
You may also request a return order for equipment that is being returned for non-warranty repair, but you will be liable for the cost of the return order.
- 2 Clean and disinfect the equipment before returning it to us. We will charge a processing fee for cleaning and disinfecting contaminated equipment. Equipment that is greatly contaminated will be returned at the customer's expense.
- 3 **Secure the corresponding transport fasteners!**
- 4 Enclose written information explaining the reason for returning the equipment.
- 5 If the equipment is being returned for credit, you must include all accessories (power cord, software media, manuals, etc.).
- 6 Return the equipment in its original packaging. If you no longer have the original packaging, you may purchase replacement packaging from Gonotec.
- 7 Do you have a high sample volume and/or cannot afford downtime?
During the warranty time, we will provide you with a temporary unit at no cost. Transport costs are only incurred outside the warranty period.

Before Calling Gonotec

Note: When calling Gonotec, have your unit's serial number ready. The serial number helps our service technicians to more quickly record the unit and determine a procedure.

If possible, switch on the unit before calling Gonotec's technical service. Use a telephone that is close to the unit. You may be asked to provide detailed information while running operations or apply other troubleshooting methods that can only be performed on the unit itself. Ensure that you have the equipment documentation handy.



Warning: Before undertaking any work on the equipment, read the safety notices in the appropriate chapters of this manual.

Tel.: +49 (030) 7809588-0
toll-free (Germany only!):
0800-7846027

Specifications

■ Overview

(Standard model)

Sample volume:	20 µl
Start-up Time:	immediately from standby and power on
Test Time:	Approx. 20 seconds
Reproducibility:	± 2 digits (20 µl) at 100 mmol/l
Measurement display:	0 - 999 mmol/l
Measuring range:	10 - 999 mmol/l
Resolution:	1 mmol/l over the entire measurement range
Integrated stirrer	PTFE magnetic stir bar, cylindrical
Environment:	Indoor use; no direct sunlight
Operating temperature (ambient):	10°C to 35°C / 50°F to 95°F
Storage temperature:	-40°C to 70°C / -40°F to 158°F
Room humidity:	5-80% (non-condensing)
Altitude:	up to 2000 m
Electrical Voltage:	100-120 VAC / 200-240 VAC
Frequency:	50-60 Hz
Power:	20 VA
Mains connection:	Detachable power supply cord
Fuses (2):	0.5 A for 200-240 VAC
(HBC breaking capacity 1500 A)	1.0 A for 100-120 VAC
Memory backup:	integral lithium cell: 10 years typical
Overvoltage category:	I
Pollution degree:	2
Protection Rating:	IP21
Dimensions (WDH) :	205 x 220 x 360 mm 8 x 8.7 x 14.2 inches
Weight (Net):	5.7 kgs. / 12.54 lbs.

(Options)

Printer (Option D):	Graphical dot matrix printer date, time and sample information on each measurement
Number of digits:	≥16 characters per row
Paper:	Normal paper, 43mm wide
Printer function:	various print modes: single print, batch printing
Error message:	Printed in plain text
Communications (Option COM):	2 x RS232, (one RS232 reserved for barcode reader); 1 x USB

Manufacturer:

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